DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 26, 2017

Fotona d.d.
Stojan Trost
Quality Assurance and Regulatory Affairs Manager
Stegne 7
1210 Ljubljana
Slovenia

Re: K070355
Trade/Device Name: Fotona Fidelis III Er:YAG/Nd:YAG Laser System Family
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: February 22, 2008
Received: February 27, 2008

Dear Stojan Trost:

This letter corrects our substantially equivalent letter of December 16, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4. Indications for Use Statement

510(k) Number (if known):

Device Name: **Fotona Fidelis III Er:YAG/ Nd:YAG Laser System Family**

Indications For Use:

Er:YAG laser (2940 nm wavelength) in dentistry:

- Intra-oral soft tissue surgery (incision, excision, ablation coagulation)
- Leukoplakia
- Pulpotomy as adjunct to root canal retreatment
- Pulp extirpation
- Removal of fibromae
- Removal of granulated tissue
- Caries removal, cavity preparation, enamel roughening
- Sulcular debridement
- Tooth preparation to obtain access to root canal, root canal debridement and cleaning, root canal preparation including enlargement
- Cutting, shaving, contouring and resection of oral osseous tissue (bone)
- Osteotomy, osseous crown lengthening, osteoplasty
- Apicectomy surgery

Er:YAG laser (2940 nm wavelength) in dermatology and other surgical areas:

- Dermatology and Plastic Surgery Indications: Epidermal nevi, actinic cheilitis, verrucae, skin tags, keratoses and skin resurfacing;
- ENT Surgery Indications: ENT lesions, cysts, polyps, hyperkeratosis, oral leukoplakia;
- Oral/Maxillofacial Indications: Oral and glossal lesions, gingivectomy;
- General Surgery Indications: Surgical incision/excision, vaporization and coagulation of soft tissue during any general surgery application where skin incision, tissue dissection, excision of lesions, complete or partial resection of internal organs, lesions, tissue ablation and vessel coagulation;
- Podiatry Indications: Warts, plantar verrucae, large mosaic verrucae, matrixectomy;

Nd:YAG laser (1064 nm wavelength) in dentistry:

- Excisional and incisional biopsies
- Excision and vaporization of herpes simplex I and II
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy and frenotomy
- Gingival troughing for crown impressions
- Gingivectomy

Neil R.P. Ogden for mxm

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

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- Gingivoplasty
- Gingival incision and excision
- Hemostasis
- Implant recovery
- Incision and drainage of abscess
- Laser assisted uvulopaletoplasty (LAUP)
- Operculectomy
- Oral papillectomies
- Pulpotomy and pulpotomy as an adjunct to root canal therapy
- Reduction of denture hyperplasia
- Reduction of gingival hypertrophy
- Removal of filling material such as gutta percha or resin as adjunct treatment during root canal therapy
- Removal of post-surgical granulations
- Soft tissue crown lengthening
- Sulcular debridement or soft tissue curettage (removal of diseased or imflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss, and tooth mobility)
- Tissue retraction for impression
- Treatment of aphtous ulcers
- Vestibuloplasty
- Laser assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium)

Nd:YAG laser (1064 nm wavelength) in dermatology and other surgical areas:

- Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin
- Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemaongiomae, warts, telangiectasiae, rosacea, venus lake, leg veins and spider veins
- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris

Prescription Use: __X___ AND/OR Over-The-Counter Use:_____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Neil R P Ogden for MXM
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K070355

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5. 510(k) Summary

Submitter's Name: Fotona d.d.
Stegne 7
1210 Ljubljana, Slovenia
Phone: +386 15009100
Fax: + 386 5009 200

Contact Person: Stojan Trošt, QA&RA Manager
Phone: + 386 1 5009 299
E-mail: stojan.trost@fotona.si

MAR - 4 2008

Date: January 31, 2007

Device Name:

Trade name: Fotona Fidelis III Er:YAG/Nd:YAG Laser System Family

Common name: Er:YAG/Nd:YAG Surgical Laser

Classification name: Instruments, Surgical, Powered, Laser
79-GEX

DEVICE DESCRIPTION

The Fotona Fidelis III laser system family is based on Er:YAG (2940 nm) and Nd:YAG (1064 nm) laser technology. It combines two flashlamp-pumped laser sources in one housing, with optical cavities containing the Er:YAG and Nd:YAG crystals. A red diode aiming beam (650 nm) is combined with both therapeutic laser beams. The combined therapeutic and aiming beams are guided through an articulated arm to an optical hand piece (in the case of the Er:YAG laser), or through an optical fiber delivery system to an optical hand piece (in the case of the Nd:YAG laser).

The Er:YAG laser is capable of delivering up to 1.5 J of laser energy in pulses with durations of up to 1000 μs and frequencies (repetition rates) of up to 50 Hz. The maximum average output power is 20 W.

For aesthetic indications, the Nd:YAG laser is capable of delivering laser fluences up to 300 J/cm^2 in pulses with durations of up to 25 ms. For dental indications, it is capable of delivering laser pulses with durations of up to 320 μs, frequencies (repetition rates) up to 100 Hz and a maximum output power of 15 W.

Fotona's power supply Variable Square Pulse (VSP) Technology, integrated into the laser system, allows ultimate control of the laser energy and the laser pulse duration. This ensures treatment precision, patient comfort, safety and ease-of-use in all treatments.

INTENDED USE

The **Fidelis III Er:YAG laser**, and its accessories, are intended for use in dentistry, dermatology and other surgical areas in the following procedures:

In **dentistry**, for:

- Caries removal, Cavity Preparation, Enamel Roughening
- Intra-oral soft tissue surgery (incision, excision, ablation, coagulation)
- Leukoplakia

- Removal of fibromae
- Removal granulated tissue
- Sulcular debridement
- Apicectomy surgery
- Cutting, shaving, contouring and resection of oral osseous tissue (bone)
- Osteotomy,osseous crown lengthening, osteoplasty
- Tooth preparation to obtain access to root canal, root canal debridement and cleaning, root canal preparation including enlargement
- Pulp extirpation
- Pulpotomy as adjunct to root canal retreatment

In **dermatology and other surgical areas,** for:

- Dermatology and Plastic Surgery Indications: Epidermal nevi, actinic cheilitis, skin tags, keratoses, verrucae, and skin resurfacing
- ENT Surgery Indications:ENT lesions, cysts, polyps, hyperkeratosis, oral leukoplakia
- Oral/Maxillofacial Indications: Oral and glossal lesions, gingivectomy
- General Surgery Indications: Surgical incision/excision, vaporization and coagulation of soft tissue during any general surgery application where skin incision, tissue dissection, excision of lesions, complete or partial resection of internal organs, lesions, tissue ablation and vessel coagulation
- Podiatry Indications: warts, plantar verrucae, large mosiac verrucae, matrixectomy

The **Fidelis III Nd:YAG laser**, and its accessories, are intended for use in dentistry, dermatology and other surgical areas in the following procedures:

In **dentistry,** for:

- Excisional and incisional biopsies
- Excision and vaporization of herpes simplex I and II
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy and frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis
- Implant recovery
- Incision and drainage of abscess
- Laser assisted uvulopaletoplasty (LAUP)
- Operculectomy
- Oral papillectomies
- Reduction of denture hyperplasia
- Reduction of gingival hypertrophy
- Removal of post-surgical granulations
- Soft tissue crown lengthening

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- Sulcular debridement or soft tissue curettage (removal of diseased or imflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss, and tooth mobility)
- Tissue retraction for impression
- Treatment of aphtous ulcers
- Vestibuloplasty
- Laser assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium)
- Pulpotomy and pulpotomy as an adjunct to root canal therapy
- Removal of filling material such as gutta percha or resin as adjunct treatment during root canal therapy

In **dermatology and other surgical areas,** for:

- Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin
- Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemaongiomae, warts, telengiectasiae, rosacea, venus lake, leg veins and spider veins
- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris

STATEMENT OF SUBSTANTIAL EQUIVALENCE

The Fidelis III laser system family shares the same indications for use, similar design and functional features with, and therefore Fotona d.d. believes that its Fidelis III laser system family is substantially equivalent to, the

a) Fotona Fidelis Er:YAG Laser System (K001527) previously cleared for incision, excision, vaporization, ablation and coagulation of soft and hard tissue in the mouth;

b) Fotona Fidelis Plus Nd:YAG Laser System (K024204) previously cleared as an accessory for Fotona Fidelis Er:YAG Laser System (K001527) for incision, excision and coagulation of intra oral soft tissue, including the marginal and inter dental gingiva;

c) Fotona XP Plus Nd:YAG Family (K050293) previously cleared for surgical and aesthetic applications in soft tissue in the medical specialities of general and plastic surgery and dermatology;

d) Fotona Dualis Nd:YAG/Er:YAG Laser System (K021548) previously cleared for surgical incision/excision, vaporization and coagulation of soft and hard tissue;

e) Hoya ConBio -VersaWave Dental Er:YAG Laser System (K041710) previously cleared for various hard tissue and soft tissue dental indications;

f) Millennium Periolase Nd:YAG Laser System (K030290) previously cleared for various dental indications;

g) Cooltouch Nd:YAG Laser System previously cleared for the treatment of mild to moderate inflammatory acne vulgaris (K040131).

h) Laserscope Gemini Laser System previously cleared for the treatment of mild to moderate inflammatory acne vulgaris (K034011)

Details are provided in the Substantial Equivalence Discussion Section of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Fotona d.d.
% Stojan Trošt
QA & RA Manager
Stegne 7
1210 Ljubljana, Slovenia

MAR - 4 2008

Re: K070355
Trade/Device Name: Fotona Fidelis III Er:YAG/Nd:YAG Laser System Family
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 22, 2008
Received: February 27, 2008

Dear Stojan Trošt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070355 Pg 1 of 2

4. Indications for Use Statement

510(k) Number (if known):

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Er:YAG laser (2940 nm wavelength) in dentistry:

- Intra-oral soft tissue surgery (incision, excision, ablation coagulation)
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- Pulp extirpation
- Removal of fibromae
- Removal of granulated tissue
- Caries removal, cavity preparation, enamel roughening
- Sulcular debridement
- Tooth preparation to obtain access to root canal, root canal debridement and cleaning, root canal preparation including enlargement
- Cutting, shaving, contouring and resection of oral osseous tissue (bone)
- Osteotomy, osseous crown lengthening, osteoplasty
- Apicectomy surgery

Er:YAG laser (2940 nm wavelength) in dermatology and other surgical areas:

- Dermatology and Plastic Surgery Indications: Epidermal nevi, actinic cheilitis, verrucae, skin tags, keratoses and skin resurfacing;
- ENT Surgery Indications: ENT lesions, cysts, polyps, hyperkeratosis, oral leukoplakia;
- Oral/Maxillofacial Indications: Oral and glossal lesions, gingivectomy;
- General Surgery Indications: Surgical incision/excision, vaporization and coagulation of soft tissue during any general surgery application where skin incision, tissue dissection, excision of lesions, complete or partial resection of internal organs, lesions, tissue ablation and vessel coagulation;
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Nd:YAG laser (1064 nm wavelength) in dentistry:

- Excisional and incisional biopsies
- Excision and vaporization of herpes simplex I and II
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy and frenotomy
- Gingival troughing for crown impressions
- Gingivectomy

Neil R.P. Ogden for mxm

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

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- Gingivoplasty
- Gingival incision and excision
- Hemostasis
- Implant recovery
- Incision and drainage of abscess
- Laser assisted uvulopaletoplasty (LAUP)
- Operculectomy
- Oral papillectomies
- Pulpotomy and pulpotomy as an adjunct to root canal therapy
- Reduction of denture hyperplasia
- Reduction of gingival hypertrophy
- Removal of filling material such as gutta percha or resin as adjunct treatment during root canal therapy
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- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris

Prescription Use: __X___ AND/OR Over-The-Counter Use:_____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Neil R P Ogden for MXM
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K070355